DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 19, 2014

BIO-ANALYSIS, INC.
C/O REGINA O'MEARA
PRINCIPAL
27735 TAMARA DRIVE
YORBA LINDA CA 92887

Re: K133303
Trade/Device Name: Pantex Salivary Direct Testosterone Enzyme Immunoassay (EIA) Kit,
Pantex Sample Collection Device
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: II
Product Code: JKA, CDZ
Dated: November 17, 2014
Received: November 19, 2014

Dear Ms. Regina O'Meara:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k133303

Device Name
Pantex Salivary Direct Testosterone EIA Kit
Pantex Sample Collection Device

Indications for Use *(Describe)*

The Pantex Salivary Direct Testosterone EIA Kit is an Enzyme Immunoassay (EIA) for the quantitative measurement of testosterone in human saliva collected with the Pantex Sample Collection Device. The measurement of testosterone is used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, impotence in males, and females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries and andrenogential syndromes.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
Pantex Salivary Direct Testosterone EIA Kit

Submitted by: Pantex, Division of Bio-Analysis, Inc.
1701 Berkeley Street
Santa Monica, CA 90404
USA
(310) 828-7423

Company Contact: Romulo Garza, Ph.D., President & Senior Scientist

Date: 10/27/14

Trade Name: Pantex Sample Collection Device
Common Name: Blood Specimen Collection Device
Regulation Number and Panel: 862.1675 / Clinical Chemistry (75)
Classification Product Code: JKA
Classification: Class II

Trade Name: Pantex Salivary Direct Testosterone EIA Kit
Common Name: Enzyme immunoassay, Testosterone, salivary
Regulation Number and Panel: 862.1608 / Clinical Chemistry (75)
Classification Product Code: CDZ
Classification: Class I, Reserved

Predicate Device:

Device Name:	Testosterone Luminescence Immunoassay
Company:	IBL International GMBH
510(k) Reference:	K033786

1. **Device Description**:

a. Test principle

The Pantex Salivary Direct Testosterone EIA kit, Cat # 635 is based on the competition principal and microplate separation. Testosterone calibrators of known concentration, unknown amounts of testosterone in saliva samples and a fixed amount of testosterone (analog) conjugated to horse radish peroxidase (Testosterone-HRP) compete for binding sites with a rabbit monoclonal antiserum bound to GARGG (goat anti-rabbit gamma globulin) coated wells of a microplate. After incubation, unbound components are washed away, enzyme substrate solution is added and a blue color formed. This reaction is stopped with an acid solution to produce a yellow color. The optical density is then read at 450 nm. The amount of Testosterone-HRP detected is inversely proportional to the amount of testosterone in a sample.

b. Pantex Sample Collection Device

The Pantex collection device is a 10 mL, non-sterile, plain polypropylene tube with a screw cap. It is provided as 50 units per package. The expiration date of the Pantex Sample Collection Device is 48 months from the day of manufacture.

c. Kit Contents

The kit consists of a 96 well GARGG (goat anti-rabbit gamma globulin) coated microplate (12x8 breakable strip wells), one concentrated stock testosterone calibrator (62,500 pg/ml), one stock testosterone control (40,000 pg/ml), both traceable to the USP, Anti-Testosterone (rabbit monoclonal), 20X concentrated testosterone-peroxidase (analog), substrate solution, stop reaction solution and 10X concentrated wash solution.

d. Intended Use

The Pantex Salivary Direct Testosterone ELA Kit is an Enzyme Immunoassay (EIA) for the quantitative measurement of testosterone in human saliva collected with the Pantex Sample Collection Device. The measurement of testosterone is used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, impotence in males, and females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries and andrenogential syndromes.

2. Technology Comparison

	Predicate Device: IBL Testosterone LIA (k033786)	New Device: Pantex Salivary Direct Testosterone EIA Kit (k133303)
Indications for use	Luminescence Immunoassay (LIA) for the in-vitro diagnostic quantitative measurement of testosterone in saliva. Measurement of testosterone (a male sex hormone) is used in the diagnosis of treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, impotence in males and in females, hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries and adrenogenital syndromes.	The Pantex Salivary Direct Testosterone EIA Kit is an Enzyme Immunoassay (EIA) for the quantitative measurement of testosterone in human saliva collected with the Pantex Sample Collection Device. The measurement of testosterone is used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, impotence in males and in females, hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries and adrenogenital syndromes.
Analyte	Free Testosterone	Free Testosterone
Sample Type	Saliva	Saliva
Method	Luminescence Immunoassay	Enzyme Immunoassay

<table>
<tr><td>Detection Method</td><td>Microplate Luminometer reader</td><td>Microplate Colormetric reader</td></tr>
<tr><td>Test Principle</td><td>Luminescence immunoassays (LIA) are based on the competition principle. An unknown amount of antigen present in the sample and a fixed amount of enzyme labeled antigen compete for the binding sites of the antibodies coated onto the wells of a microplate. After incubation the wells are washed to stop the competition reaction. After addition of the luminescence substrate solution, the intensity of the luminescence measured is inversely proportional to the amount of the antigen in the sample. Results of samples can be determined directly using the standard curve.</td><td>Enzyme Immunoassays (EIA) are based on the competition principle. An unknown amount of antigen in the sample and a fixed amount of enzyme labeled antigen compete for the binding sites of antibodies coated onto a GARGG coated microplate. After incubation, the microplate is washed to stop the competition reaction and remove unbound components. After addition of the enzyme substrate (TMB) solution, color is formed and the optical density read. The intensity of the color measured is inversely proportional to the amount of the antigen present in the sample. Results of samples can be determined directly using the standard curve.</td></tr>
<tr><td>Calculations</td><td>Quantitative determination with standard curve</td><td>Quantitative determination with standard curve</td></tr>
<tr><td>Quality Control</td><td>Use of reference controls is recommended</td><td>Use of reference controls is recommended</td></tr>
<tr><td>Analytical Measuring Range (AMR)</td><td>2.0 pg/mL – 500 pg/mL</td><td>6.4 pg/mL – 500 pg/mL</td></tr>
<tr><td>Expected Values (Normal range)</td><td>Female
Age | Median | Range 5-95% | N
20-29 | 19.0 | 5.5-49.0 | 40
30-39 | 17.3 | 5.2-49.0 | 39
40-49 | 13.8 | 4.5-49.0 | 47
50-59 | 13.2 | 3.6-49.0 | 53
60-69 | 15.8 | 2.9-38.8 | 33
Male
20-29 | 78.8 | 41.4-142.5 | 55
30-39 | 58.8 | 31.8-100.4 | 35
40-49 | 54.4 | 30.1-97.8 | 48
59-59 | 54.8 | 30.0-92.0 | 64
60-69 | 42.9 | 23.2-86.9 | 63</td><td>Female
Age | Median (pg/mL | 95% ref. limits | 90% CI (pg/mL) | N
20-49 | 17.20 | 3.91 -40.9 | 3.70 -50.0 | 120
50-70 | 14.75 | 4.51-34.17 | 4.2 -35.1 | 120
Male
20-49 | 86.6 | 41.12-142.16 | 33.6-157.9 | 120
50-70 | 60.15 | 24.03-119.52 | 22.0-131.9 | 120</td></tr>
<tr><td>Limits of Detection</td><td>Analytical Sensitivity = 1.8 pg/mL</td><td>Limit of Blank (LoB)
1.8 pg/mL
Limit of Detection (LoD)
2.1 pg/mL
Limit of Quantitation (LoQ)
3.9 pg/mL</td></tr>
<tr><td>Saliva Collection Device</td><td>IBL Saliva Sampling Set (conical polypropylene tubes with 2.0 mL capacity).</td><td>Pantex sample collection device, Cat # PCD602. The Pantex collection device is a 10 mL, non-sterile, plain polypropylene tube with a screw cap. The expiration date of the device is 48 months from the day of</td></tr>
</table>

		manufacture.
Interference	Did not test for interferences in salivary testosterone measurement when testing with caffeine, food, nicotine, alcohol. or chewing gum.	An in-vivo study with caffeine, food, nicotine, alcohol and chewing gum did not reveal significant interference in the measurement of testosterone in saliva using the Pantex Salivary Direct Testosterone EIA Kit, Cat #635.
Stability and Storage of Kit reagents	Stated as stable at 2-8°C until kits expiration date	4 months at 2-8°C. The stability study is still on-going.

Table Continues

3. Test Summary

Performance Characteristics

The performance characteristics of the Pantex Salivary Direct Testosterone EIA Kit were based on evaluations by the following analytical performance tests. All saliva samples used in the performance testing were collected and processed through the Pantex Sample Collection Device (Cat # PCD602).

a. Precision/Reproducibility

The intra-assay precision was determined from 20 replicates of low, medium and high saliva pools.

Sample	N	Mean (pg/mL)	Standard Deviation (pg/mL)	%CV
Low	20	21.0	1.063	5.1
Medium	20	174.7	3.641	2.1
High	20	318.7	13.517	4.2

The inter-assay precision was determined from the mean of the average of duplicates for 12 separate assays with low, medium and high saliva pools.

Sample	N	Mean (pg/mL)	Standard Deviation (pg/mL)	%CV
Low	12	19.1	1.232	6.4
Medium	12	155.6	7.106	4.6
High	12	285.5	8.847	3.1

The inter-lot precision was determined by duplicate measurements of five (5) saliva samples and two levels of one (1) spiked control in saliva like matrix, using three (3) different reagent lots. The results of intra-assay, inter-assay and inter-lot variation concluded a %CV of ≤10% for each sample tested.

Saliva Samples ID	Lot # 007 mean (pg/ml)	Lot # 008 mean (pg/ml)	Lot # 009 mean (pg/ml)	Inter-lot mean (pg/ml)	Inter-lot Std. Dev. (pg/ml)	Inter-lot %CV (pg/ml)
1	314.6	324.0	320.1	319.6	4.723	1.5
2	101.8	97.4	99.3	99.5	2.207	2.2
3	69.2	69.4	61.0	66.5	4.793	7.2
4	8.8	9.7	9.9	9.5	0.586	6.2
5	23.8	21.7	21.3	22.3	1.343	6.0
C1	21.1	19.5	20.5	20.4	0.808	4.0
C2	210.2	196.3	212.2	206.2	8.660	4.2

Repeatability

This study was conducted during 5 days of a familiarization period and 20 days of testing. Two assays were performed daily with a minimum of 1 hour between assays. Three (3) different reagents lots and three (3) saliva pools were used for the study (low, medium and high concentration). The pools were aliquoted and frozen until the day of assay.

Precision Study Data Summary

Sample Concentration	N	Mean (pg/mL)	Repeatability		Total Precision	
			SD	%CV	SD	%CV
Low	100	19.4	0.8	3.8	1.1	5.6
Medium	100	155.3	3.7	2.5	7.9	5.3
High	100	275.6	7.4	2.5	11.9	4.0
Control 1	100	19.3	0.9	4.6	1.2	5.8
Control 2	100	201.4	3.8	1.8	8.2	4.0

b. Linearity

Ten (10) sample concentrations that span the assay measuring range were prepared and assayed per CLSI EP6-A, Evaluation of the Linearity of Quantitative Measurement Procedures.
S=10 samples (dilutions)
Concentration = (C1*V1 + C10*V10)/(V1+V10)

	C1 pg/ml	V1 ml	C10 pg/ml	V10 ml	Calculated Concentration pg/ml	Observed Concentration pg/ml	Recovery %
1				*	5.5	5.2	94.5
2	5.2	0.889	631.5	0.111	74.7	76.3	102.1
3	5.2	0.778	631.5	0.222	144.2	153.6	106.5
4	5.2	0.667	631.5	0.333	213.8	216.1	101.1
5	5.2	0.556	631.5	0.444	283.3	275.3	97.2
6	5.2	0.444	631.5	0.556	353.4	323.6	91.6
7	5.2	0.333	631.5	0.667	422.9	401.8	95.0
8	5.2	0.222	631.5	0.778	492.5	461.7	93.8
9	5.2	0.111	631.5	0.889	562.0	561.4	99.9
10				*	650.0	631.5	97.2

***** Targets of low and high sample concentrations.

The results demonstrate that the assay is linear from 5.5 – 650.0 pg/mL.
($Y=0.9597x + 3.335$, $R^2 = 0.99685$)

c. Recovery

Seven (7) saliva samples containing different levels of endogenous testosterone were spiked with known quantities of testosterone and assayed.

Sample	Endogenous (pg/ml	Added (pg/ml)	Expected (pg/ml)	Observed (pg/ml)	Recovery (%)
1	10.000	7.813	17.813	19.400	108.9
2	19.000	15.625	34.625	36.300	104.8
3	27.600	31.250	58.850	54.500	92.6
4	28.200	62.500	90.700	95.100	104.9
5	9.800	125.000	134.800	127.900	94.9
6	103.700	250.000	353.700	346.800	98.0
7	38.600	500.000	538.600	497.600	92.4

d. Manual Dilution

A 1:10 sample manual dilution study was performed utilizing six (6) samples to verify the accuracy of the dilution procedure with a dilution factor of 10. The following table indicates the summary of results:

Subject	Observed Endogenous Value (pg/mL)	Testosterone Spiked (pg/mL)	Expected Value (pg/mL)	Observed 1:10 diluted Value (pg/mL)	Applied Factor 10 (pg/mL)	Recovery (%)
AL-209	346.7	0	346.7	33.3	333	96.0
AL-210	274.3	0	274.3	26.5	265	96.6
*AL-225	133.1	500	633.1	67.2	672	106.1
AL-227	229.5	0	229.5	22.7	227	98.9
*AL-228	100	750	850	93.1	931	109.5
*AL-247	125.8	1000	1125.8	121.3	1213	107.7

* Spiked samples.

4. Reagent Stability/Sample Stability/Expected Values

The long term stability study for reagents stored at 2 – 8° C is currently on-going; however, at the time of this executive summary report the expiration date supported by the results obtained on the stability study is 4 months from the manufacturing date when the reagents are stored at 2 – 8° C. As the stability study progresses, the expiration date will be upgraded accordingly.

a. **Open Vial Stability**

Condition	Stability	Storage Temperature
Open vial stability	31 days	2 - 8°C
Working Testosterone-HRP Conjugate solution	31 days	2 - 8°C
Diluted working testosterone stock calibrator	31 days	2 - 8°C
Diluted working testosterone stock control	31 days	2 - 8°C

b.Sample Stability

Storage	20-28°C	37°C	2-8°C	≤-15°C (7 freeze/thaw cycles)	≤-15°C (Long term)
Stability	Up to 7 days	Up to 7 days	Up to 7 days	Up to 7 days	Up to 180 days

c. Sample Shipping, Handling and Storage Conditions Stability

The samples were shipped to a location outside the testing site on 7/2/14 and returned to the testing site on 7/11/14 representing a total of 9 days in transit; thereafter, the samples were stored at 2-8ºC, 20-28ºC, 37ºC and ≤-15ºC for 7 days and tested after 3 days and 7 days. Based on the results obtained, it appears that the samples retained their physical integrity and testosterone levels remained unaffected for 9 days in transit and up to 7 days when stored at the stated temperatures.

Storage	2-8°C and room temperature during transit	20-28°C	37°C	2-8°C	≤-15°C
In transit stability upon return to the testing site	Up to 9 days				
After returning stability		Up to 7 days	Up to 7 days	Up to 7 days	Up to 7 days

5. Expected Reference Values:

The reference range was established by testing 120 male saliva samples and 120 female saliva samples to have an equal number of male and female samples. The reference range and median were calculated using CLSI C28-A3 as a guide. The following tables indicate the summary of the results.

Female Expected Values:

Subjects (Number)	Age (Age)	Median (pg/mL)	95% Reference Limits (pg/mL)	90% CI (pg/mL)
120	20-49	17.20	3.91 – 40.99	3.70 – 50.0
120	50-70	14.75	4.51 – 34.17	4.2 – 35.1

Male Expected Values:

Subjects (Number)	Age (Age)	Median (pg/mL)	95% Reference Limits (pg/mL)	90% CI (pg/mL)
120	20-49	86.6	41.12 – 142.16	33.6 – 157.9
120	50-70	60.15	24.03 – 119.52	22.0 – 131.9

6. Detection Limits:

The Detection Limit Study for determining the limit of the blank (LoB), limit of detection (LoD) and the limit of quantitation (LoQ) for the Pantex Salivary Direct Testosterone EIA Kit, Cat #635 was performed using several low testosterone samples and two different reagent lot numbers that were assayed twice per day over a period of 3 days. (Reference, CLSI EP 17-A, protocols for Determination of Limits of Detection and Limits of Quantitation).

Limit of the Blank (LoB) pg/mL	Limit of Detection (LoD) pg/mL	Limit of Quantitation (LoQ) pg/mL
1.8	2.1	3.9

7. Analytical Specificity/Cross Reactivity

The cross reactivity of the antiserum was determined by spiking three (3) saliva pools (low, medium and high) with two (2) concentrations (10,000 pg/ml and 20,0000 pg/mL) of each potential cross reactant. The percent cross reaction was calculated using the following equation as per CLSI (EP7-A2) guidelines.

$$\text{The \% Cross-reactivity} = 100^{*} \frac{[\text{measured value} - \text{true value}]}{[\text{concentration of interferant}]}$$

Where, *Measured value = is the spiked measured value and True value = is the un-spiked obtained value and concentration of interferant = is the amount of the compound spiked*

Compound	Low Testosterone sample (% Cross Reactivity)	Medium Testosterone Sample (% Cross Reactivity)	High Testosterone sample (% Cross Reactivity)
Testosterone	100	100	100
11 β-OH Testosterone	0.407	0.486	0.242
11 α-OH Testosterone	0.869	1.033	0.601
5 α-Dihydro-Testosterone	5.540	5.474	5.347
Androstenedione	0.718	0.876	0.604
Methyl Testosterone	1.410	1.597	0.889
Testosterone SO4	0.005	0.010	0.067
DHEA SO4	0.001	0.001	0.006
DHEA	0.001	0.003	0.006
7-Keto DHEA	0.003	0.004	0.008
Progesterone	0.243	0.276	0.179
Cortisol	0.005	0.002	0.005
17 β-Estradiol	0.175	0.173	0.135
17 α-Estradiol	0.007	0.002	0.008
Cortisone	0.014	0.013	0.013
Danazol	0.011	0.018	0.063
Dexamethasone	0.007	0.025	0.051
D-5-Androstene-3 β, 17 β -diol	0.691	0.827	0.497
Estrone	0.015	0.003	0.012
Ethisterone	0.037	0.050	0.084
Norgestrel	0.033	0.020	0.071

Testosterone propionate	0.068	0.065	0.134
5 α-Androstane-3 β, 17 β-diol	2.497	2.745	2.571
11-Keto Testosterone	0.137	0.158	0.079
Prednisone	0.038	0.009	0.018
Prednisolone	0.023	0.007	0.028

8. Method Comparison Studies

A comparative study was performed between the Pantex Salivary Direct Testosterone EIA Kit Cat #635 and a FDA cleared predicate device. A total of 106 samples were used for the study (range 6.45–458.35 pg/ml) of which 9 samples were spiked representing 8.5 % (range 252.1 – 424.2 pg/mL) of the total number of samples. The results show the following regression and correlation statistics.

Linear Regression equation	Y = 0.9035X + 5.81
Correlation	R2 = 0.98

Traceability

The synthetic Testosterone used in the manufacturing of the Testosterone Stock Calibrator and the Testosterone Stock Control is traceable to the U.S. Pharmacopeia (USP) catalog number 1646009, Lot number J0G360.

9. Interference Studies

Using CLSI-A2 Interference Testing in Clinical Chemistry as a guide, an in-vivo simulated experiment was performed after collecting saliva samples from subjects before (control) and after contact (exposed) with five (5) commonly consumed products (coffee, food, gum, alcohol and cigarette smoke). The control and exposed samples were tested with the Pantex Salivary Direct Testosterone EIA Kit, Cat #635. The results indicated no significant differences in salivary testosterone values between the controls and exposed samples.

In-vivo simulated experiment results

Sample ID	Interference Substance	Collection Time	Observed value (pg/mL)	Recovery from Control
JGA-Day1	No food	8:00 AM	23.1	
JGB-Day1	Food	8:15 AM	22.5	97.4
JGA-Day 2	No coffee	8:00 AM	25.7	
JGB-Day 2	Coffee	8:15 AM	26.2	101.9
JGA-Day3	No wine	8:00 AM	21.8	
	Wine	8:15 AM	22.0	100.9
JGA-Day 4	No gum	8:00 AM	15.4	
	Gum	8:15 AM	16.2	105.2
JGA-Day 5	No smoke	8:00 AM	25.5	
	Smoke	8:15 AM	25.3	99.2
Sample ID	Interference Substance	Collection Time	Observed value (pg/mL)	Recovery from Control
MGA-Day1	No food	8:00 AM	42.0	
MGB-Day1	Food	8:15 AM	39.2	93.3
MGA-Day 2	No coffee	8:00 AM	41.1	
MGB-Day 2	Coffee	8:15 AM	39.9	97.1
MGA-Day3	No wine	8:00 AM	28.4	
MGB-Day 3	Wine	8:15 AM	29.0	102.1
MGA-Day 4	No gum	8:00 AM	47.1	
MGB-Day 4	Gum	8:15 AM	46.8	99.4
MGA-Day 5	No smoke	8:00 AM	40.0	
MGB-Day 5	Smoke	8:15 AM	38.7	96.8
DGA-Day1	No food	8:00 AM	86.1	
DGB-Day1	Food	8:15 AM	87.9	102.1
DGA-Day 2	No coffee	8:00 AM	63.1	
DGB-Day 2	Coffee	8:15 AM	65.5	103.8
DGA-Day3	No wine	8:00 AM	123.9	
DGB-Day 3	Wine	8:15 AM	118.7	95.8
DGA-Day 4	No gum	8:00 AM	99.1	
DGB-Day 4	Gum	8:15 AM	101.0	101.9
DGA-Day 5	No smoke	8:00 AM	70.5	
DGB-Day 5	Smoke	8:15 AM	71.7	101.7

Table Continues

Sample ID	Interference Substance	Collection Time	Observed value (pg/mL)	Recovery from Control
RGA-Day1	No food	8:00 AM	43.7	
RGB-Day1	Food	8:15 AM	41.3	94.5
RGA-Day 2	No coffee	8:00 AM	41.7	
RGB-Day 2	Coffee	8:15 AM	43.8	105.0
RGA-Day3	No wine	8:00 AM	33.1	
RGB-Day 3	Wine	8:15 AM	32.6	98.5
RGA-Day 4	No gum	8:00 AM	36.8	
RGB-Day 4	Gum	8:15 AM	37.3	101.4
RGA-Day 5	No smoke	8:00 AM	35.4	
RGB-Day 5	Smoke	8:15 AM	36.9	104.2

Using CLSI-A2 as a guide, an interference study was conducted using three (3) potential interferants whole blood, sodium azide and thimerosal to determine their effects on salivary testosterone samples. The interferants were tested using the following concentrations 0.05%, 0.10%, 0.25% and 0.5%. Based on the results, it was determined that whole blood, thimerosal and sodium azide affect salivary testosterone samples by either increasing or suppressing testosterone values. Saliva samples containing any of the three interferants in question should be avoided when using the Pantex Salivary Direct Testosterone EIA Kit, Cat # 635.

10. **Conclusion**:

Taken together, the performance characteristics, comparison studies with a predicate device and acceptable statistical performance studies in this 510(k) Class I Reserved submission demonstrates that the Pantex Salivary Direct Testosterone EIA Kit, Cat #635, is safe and effective for its intended use and is substantially equivalent to the predicate device